



REGISTRATION DECISION

***Chondrostereum
purpureum***
strain PFC2139
***Cp*-PFC2139**
Chontrol Paste

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Registration Decision for *Chondrostereum purpureum* strain PFC2139

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#) and in accordance with the Pest Control Products Regulations, is granting full registration for the sale and use of active ingredient Cp-PFC2139 (containing the microbial pest control agent *Chondrostereum purpureum* strain PFC2139) and the end-use product Chontrol Paste for the inhibition of stump resprouting in Sitka and red alder trees.

Current scientific data from the applicant were evaluated to determine if, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for full registration in the Consultation Document¹: Proposed Registration Decision [PRD2007-03](#), *Chondrostereum purpureum* strain PFC2139 Chontrol Paste. This Registration Decision² describes this stage of the PMRA's regulatory process for *Chondrostereum purpureum* strain PFC2139 as well as summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2007-03 that would impact the risk assessment. This decision is consistent with the proposed registration decision stated in PRD2007-03.

For more details on the information presented in this Registration Decision, please refer to PRD2007-03, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration³. The Act also requires that products have value⁴ when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of the *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g., children) as well as organisms in the environment (e.g., those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is *Chondrostereum purpureum* strain PFC2139?

Chondrostereum purpureum strain PFC2139 is a biological herbicide. This living fungus is formulated into Chontrol Paste and applied to freshly cut stumps of weedy broadleaf brush species in rights-of-way and other forest vegetation management situations. *Chondrostereum purpureum* is a native fungus that is common throughout Canada. It invades its tree host through fresh-cut wounds and grows in the xylem, which is the principal water-conducting tissue of vascular plants. *Chondrostereum purpureum* causes death only if the infected trees are severely stressed. The presence of *C. purpureum* in broadleaf trees is expressed first as discolouration of woody tissue and later as wood decay. In some broadleaf tree species such as apple, it causes "silver leaf disease", which gets its name from the silver or leaden lustre of the tree leaves. The fungus also produces mushroom fruiting bodies on trees up to three years after initial infection.

❖ Health Considerations

◆ Can Approved Uses of *Chondrostereum purpureum* strain PFC2139 Affect Human Health?

***Chondrostereum purpureum* strain PFC2139 is unlikely to affect your health when used according to the label directions.**

Potential exposure to *C. purpureum* strain PFC2139 may occur following the release of spores and when handling and applying the product. However, the application of this microorganism is not likely to result in a significant increase in the natural environmental background levels of spores produced by this species because it is abundant throughout Canada. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (e.g., production of toxic byproducts);
- reports of any adverse incidents;
- its potential for pathogenicity, infectivity and toxicity as determined in toxicological studies; as well as
- the likely levels to which people may be exposed.

Toxicology studies in laboratory animals describe potential health effects from large doses in hopes of identifying any potential pathogenicity, infectivity and toxicity concerns. The health effects noted in animals occur at doses much higher than levels to which humans are normally exposed when using products containing *C. purpureum* strain PFC2139 according to the label directions.

No significant health effects or signs of pathogenicity or infectivity were observed when *C. purpureum* strain PFC2139 was administered to rats and rabbits. In irritation studies, Chontrol Paste was slightly irritating when applied to the skin and was minimally irritating when applied into the eye. *Chondrostereum purpureum* is not known to produce any toxins harmful to animals, and there are no known reports that it has caused adverse effects in people. However, repeated exposure to high concentrations of *C. purpureum* strain PFC2139, as with any other microorganism, can potentially lead to the development of allergic reactions.

◆ **Residues in Water and Food**

Dietary risks from food and water are not of concern.

As Chontrol Paste is not intended for application to food or feed crops, the establishment of a maximum residue limit (MRL) is not required for *C. purpureum* strain PFC2139. The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established MRL. Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Adverse effects are not expected from dietary exposure to *C. purpureum* because it will not be directly applied to food or water and its application to cut stumps is not expected to significantly increase the natural environmental background levels of this microorganism. Furthermore, this microorganism is not known to produce any mammalian toxins, and no health effects were observed in the toxicology studies. Although heavy rainfall might carry *C. purpureum* into water, this microorganism is not expected to survive and multiply in this environment. Moreover, municipal treatment of drinking water supplies would further reduce the possibility of *C. purpureum* strain PFC2139 occurring in drinking water.

◆ **Occupational Risks From Handling *Chondrostereum purpureum* strain PFC2139**

Occupational risks are not of concern when *Chondrostereum purpureum* strain PFC2139 is used according to the label directions, which include protective measures.

Pesticide applicators handling or applying Chontrol Paste and field workers re-entering areas containing freshly treated stumps can come in direct contact with *C. purpureum* strain PFC2139 on the skin. For this reason, the label will specify that anyone handling, applying or entering an area treated with Chontrol Paste must wear a long-sleeved shirt, pants and chemical-resistant gloves.

For bystanders, exposure will be low during application because Chontrol Paste is typically applied in remote areas (rights-of-way). Bystander exposure, however, may occur up to three years after application through the inhalation of spores that are released from fruiting bodies (mushrooms) on infected tree stumps. Nonetheless, the application of *C. purpureum* strain PFC2139 is unlikely to result in a significant increase of spores compared to natural background levels produced by wild strains of this fungus because this species is abundant throughout Canada.

❖ Environmental Considerations

◆ What Happens When *Chondrostereum purpureum* strain PFC2139 Is Introduced Into the Environment?

Environmental risks are not of concern.

Chondrostereum purpureum PFC2139 is a weak pathogen of broadleaf trees. Its formulation as a paste and its direct application to cut stumps are expected to minimize exposure to non-target trees. Fruiting bodies (mushrooms) may be produced on cut stumps up to three years after application. Non-target trees are most likely to be infected by spores released from the mushrooms of this fungus; however, fresh wounding and poor overall health are needed for infections to occur. No buffer zone around treated trees is required because non-target healthy trees are at negligible risk, while wounded trees are just as vulnerable to wild strains of *C. purpureum* as they are to *C. purpureum* strain PFC2139. *Chondrostereum purpureum* can be found in abundance in wooded areas across North America.

❖ Value Considerations

◆ What Is the Value of Chontrol Paste?

Chontrol Paste, a biological herbicide, inhibits stump resprouting in Sitka alder and red alder.

Chontrol Paste is a formulated product containing living mycelium of the fungus *C. purpureum* strain PFC2139 for application to freshly cut stumps of red alder and Sitka alder in rights-of-way and forest vegetation management situations. When applied according to the label directions, Chontrol Paste inhibits the resprouting and regrowth from cut stumps of red alder and Sitka alder.

The impact of Chontrol Paste on surrounding vegetation is limited because *C. purpureum* is a weak pathogen. *Chondrostereum purpureum* can only invade through fresh wounds, causing a mild sap streak in many infected trees and killing only severely compromised trees. Healthy trees repel fungal infection with antifungal metabolites and by compartmentalizing infected tissues. Given that the fungus can survive as a saprophyte (by obtaining nourishment from the products of organic breakdown and decay), there is little selection pressure toward greater virulence or host specialization.

Chontrol Paste is a non-chemical control alternative that will reduce the reliance on chemical control methods and increase the efficiency of manual or mechanical methods of control.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Chontrol Paste to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

- **Human Health**

As there is a concern with users developing allergic reactions following repeated exposure to higher than environmental levels of *C. purpureum* strain PFC2139 on the skin, anyone handling or applying Chontrol Paste must wear a long-sleeved shirt, pants and chemical-resistant gloves.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_inforserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision Document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_inforserv@hc-sc.gc.ca).

⁵ As per subsection 35(1) of the *Pest Control Products Act*.

References

| PMRA Identification Number | Reference |
|-----------------------------------|--|
| 1108295 | Toxicity/Pathogenicity Testing of Chondrostereum purpureum Following Acute Intratracheal Challenge in Rats. 2005. Study Number 2122 SN1, DACO: 4.6.8 |